



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 21 2002

NADA 140-929

Tam Garland DVM, PhD
Regulatory Manager
Elanco Animal Health/A Division of Eli Lilly and Company
2001 W. Main Street, DC GL21
Greenfield, IN 46140

Dear Ms. Garland

This correspondence is in reference to your Drug Experience Report dated February 11, 2002, concerning Micotil 300 Injection®, NADA 140-929. Your submission includes Face-to-Face Ad #1, #2, #8, and #11 and 2 Revised Bottle Ads (Single Page and Spread). We note that these pieces fail to include required information.

If these pieces are disseminated as advertisements, as you claim they are, the Face-to-Face pieces fail to include brief summary of information relating to the side effects, contraindications and effectiveness as required under 21 CFR 202.1 (e) (1). These omissions would cause your drug product to be misbranded under 502(n) of the Federal Food, Drug, and Cosmetic Act.

If these pieces are disseminated as labeling then these pieces fail to include full disclosure information, eg., the approved package insert, as required by 21 CFR 201.105 (d) (1). These omissions would cause your drug product to be misbranded under 502(n) of the Federal Food, Drug, and Cosmetic Act.

While we note the statements "*see adjoining label for complete use information, including human warnings*", in Face-to-Face ad #1 and "*see label for complete use information, including human warnings*" in pieces #2, #8 and #11, there was no "label" or package insert accompanying these pieces.

We request you immediately stop using these and other similar pieces and refrain from promoting your product in a manner that is not consistent with the applicable law.

Please inform us of your intentions as soon as possible or in any event within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely Yours

Mohammad I. Sharar, DVM, M.Sc
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine

cc:

NADA/DER 113-232 (200)

HFV-210 SDRF

HFV-212 (Dr Peterson)

HFV-214 (Dr. Vengris)

HFV-216 (Dr. Sharar)

HFR-MW 200

EHall-Robinson 05/19/2002

TMoskal 10/21/2002 *T.M.*

ec: SN140929L0392V001ltr